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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,806	01/25/2002	David Francischelli	M190.135.101	9372

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EXAMINER	
PEFFLEY, MICHAEL F	
ART UNIT	**PAPER NUMBER**
3739	15

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/056,806	FRANCISCHELLI ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 15-32* is/are rejected.

7)☒ Claim(s) *12-14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's amendments and comments, received March 8, 2004, have been fully considered by the examiner. The following is a complete response to the March 8, 2004 communication.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1-10, 19, 20 and 22-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Panescu et al ('267).

Panescu et al disclose an electrosurgical system for creating lesions in tissue. The system includes an instrument with an electrode (16), a power source (12) having multiple power settings, a controller (98) for controlling the operating parameters and a source of fluid (50) for cooling the electrode. Panescu et al teach that lesion depth may be controlled empirically or by computer modeling by controlling the power and cooling fluid delivered to an electrode. Tables 1 and 2 (col. 10) show various results of power/cooling combinations and their effect on lesion depth. Columns 9 and 10 discuss the creation of data tables or computer modeling for creating lesion depths. Column 11, lines 5-15 specifically address a controller which is used to input desired lesion depths and identifies a desired power level and treatment time. Column 12, lines 12-25 specifically discusses that the controller may fix any of a variety of variables to achieve a desired lesion.

Claim Rejections - 35 USC § 103

Claims 1-11, 15 and 22-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Panescu et al ('267).

The Panescu et al device has been addressed previously. In summary, Panescu et al teach that various parameters may be preselected and that one or more of the remaining parameters may then be varied to arrive the desired lesion characteristic (col. 12, lines 12-25). Panescu et al do not expressly state that the desired power setting is selected prior determining the energization time period and that the energization time period is selected prior to the delivery of electrical energy.

The examiner maintains that such a protocol is clearly suggested in the disclosure at column 12 even if it is not expressly stated. The specific order in which the parameters are entered is not particularly important as the remaining variables are adjusted as necessary to arrive at the desired lesion per the "dial-a-lesion" system established by Panescu et al. Furthermore, applicant has not established that there is an unexpected result associated with the particular order in which the parameters are entered, nor does applicant's disclosure establish any specific criticality in the order in which parameters are entered. Like Panescu et al, the applicant's disclosure provides a table, or plurality of tables, for associating various variables (e.g. time, power, cooling) with a desired lesion depth. It is the examiner's continued position that it would be obvious to create any number of matrices for the variables to achieve the desired lesion results.

In conclusion, to have utilized the Panescu et al system to first select a power setting and then select a time period for creating a desired lesion in tissue would have been an obvious consideration for one of ordinary skill in the art since Panescu et al clearly suggest that the controller may have input any control variable and automatically adjust the remaining variable(s) to arrive a desired lesion.

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Panescu et al as applied to the claims above, and further in view of the teaching of Mulier et al ('553).

The Panescu et al reference has been addressed previously. There is no explicit disclosure in Panescu et al of drawing the electrode back and forth across tissue to create the desired lesion pattern as part of a MAZE procedure.

Mulier et al disclose an analogous ablation system which includes a catheter with a distal electrode for ablating cardiac tissue. The lesions are to reduce conduction pathways (i.e. MAZE procedure), and Mulier et al teach that it is known to move such catheters across tissue to create the desired lesion pattern. In particular, Mulier et al provide the device with a roller electrode so that it is more smoothly moved across tissue as compared to prior art tip electrodes such as taught by Panescu et al.

To have moved the Panescu et al device across cardiac tissue to create a desired lesion pattern in tissue would have been an obvious consideration for one of ordinary skill in the art in view of the Mulier et al teaching.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Panescu et al ('267) in view of the teachings of Jackson et al ('874) and Edwards ('877).

Panescu et al fail to specifically disclose a warning signal to indicate the completion of the lesion procedure.

The examiner maintains that it is generally known in the art to provide electrosurgical systems with warning means (audio and visual) which indicate various operating conditions of the system. In support of this, Jackson et al and Edwards are provided for showing the use of such warning signals. Jackson et al provide an ablation catheter very much like the Panescu et al device which sends a warning signal when an undesirable phase shift occurs (col. 6, lines 3-8), and Edwards discloses a system for creating controllable lesions in tissue and includes a warning means alerting the user of attaining predetermined limits for energy delivery (col. 15, lines 40-50).

To have provided the Panescu et al system with a warning signal means to alert the user of attaining a desired level of treatment would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Edwards and Jackson et al.

Allowable Subject Matter

Claims 12-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed March 8, 2004 have been fully considered but they are not persuasive.

Applicant continues to assert that Panescu et al describe a physician pre-selecting a targeted ablation time and maximum power and temperature settings and therefore uses a pre-determined or preset time period and therefore cannot anticipate applicant's claim 1. The examiner agrees that Panescu et al do disclose such a system which includes a preset time. However, this is but one example of the Panescu et al system, and the system is not specifically limited to operating in that one mode. Column 12, lines 16-25 expressly state that alternative arrangements are contemplated with any of the various variables being set and any of the remaining variables being varied to produce the desired lesion output. It is the examiner's position that this disclosure is anticipatory of the newly added limitations of claim 1, or that it at least makes obvious these limitations. That is, the language in column 12, lines 16-25 expressly suggests that any of the variables may be chosen to either be preset or variable. This would be inclusive of the steps of first selecting a power setting then selecting a time period, although that specific combination is not expressly set forth. Alternatively, the examiner maintains that it would have been obvious to have selected any of the variables in any given order to establish a desired lesion based on this disclosure. Again, applicant's specification is void of any specific criticality associated with the order of selecting the variables and does not set forth any unexpected result obtained by the order in which the variables are selected.

Applicant asserts on page 9 of the latest response that "the controller 98 can fix any one or more of the control parameters" and that the passage cited at column 12 of the Panescu et al device only relates to the controller determining which of the parameters are varied. Applicant continues to state that "Since the controller 98 determines the parameters "T1", "P," and "t" during ablation, the cited passage only relates to parameters fixed/varied during, rather than prior to, ablation and does not alter what parameters the physician initially inputs into the controller 98." The examiner maintains that the physician may still input both time and energy settings prior to ablation, and the system (i.e. controller 98) uses this information to achieve the desired lesion. In particular, column 11, lines 14+ detail a specific example whereby the physician inputs the selected time (t=120 seconds), maximum tissue temperature and maximum power level P_{max}. In this example, the controller 98 selects the constant power level P of 31 Watts. Hence, both time and power have been selected prior to ablation, albeit time has been selected prior to power which is opposite to applicant's claimed selection of an energy level prior to the selection of a time period. The examiner maintains that the language of column 12, which states that any one or more of the variables T1, P or t may be fixed clearly suggests that a physician may input both a desired time (t) and power (P) prior to ablation. The order in which the variables are entered does not matter since the controller will select the remaining values prior to ablation (as disclosed in the column 11 example). For example, if the physician had selected a desired power P in the column 11 example prior to inputting a time, the physician still may be able to enter a desired time and the controller would react

accordingly. Alternatively, the physician may have entered a desired power P and the controller may select the proper time, which selection would have been made prior to the ablation procedure.

With regard to independent claim 22, applicant asserts that Panescu et al fail to disclose a look table with includes time period information organized as a dependent variable of the power setting and lesion depth and including a power setting data set that includes two of the multiple available power setting.

The examiner maintains that the Panescu et al controller 98 would have the various correlation tables as suggested at column 11, lines 1-5 where Panescu et al specifically state that the controller has a memory storing a matrix of operating conditions for the disclosed time (t) of 120 seconds and given T_{max} as well as the data "for an array of other operating conditions". The examiner maintains that the previously discussed sections of the Panescu et al patent suggest that both power and energy may be set prior to ablation (and in any order), and the controller would inherently, or at least obviously, contain data sets for these operating conditions, including multiple power settings.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Peffley
Primary Examiner
Art Unit 3739

mp
April 28, 2004